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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,490	03/04/2004		Mark Lykam		3043
32133	7590	01/04/2005		EXAMINER	
US CORPO		S, INC.	ALIE, GHASSEM		
630 NEPTUNE AVE. ENCINITAS, CA 92024				ART UNIT	PAPER NUMBER
				3724	3724
				DATE MAILED: 01/04/2004	•

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/796,490	LYKAM, MARK					
Office Action Summary	Examiner	Art Unit					
·	Ghassem Alie	3724					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM							
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 04 Ma	arch 2004.						
,	· ·						
3) Since this application is in condition for allowar							
Disposition of Claims							
4) Claim(s) 1-8 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) 1-8 is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers		·					
9) The specification is objected to by the Examine	r.	^					
10)⊠ The drawing(s) filed on <u>04 March 2004</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
235 the attached detailed office addorrior a list of the definion copies not received.							
		٠.					
Attachment(s)	·						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date							
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		Patent Application (PTO-152)					
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Oath/Declaration

Non-initialed and/or non-dated alterations have been made to the oath or declaration.
 See 37 CFR 1.52(c). See page 2 of the declaration.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a right and left torsion fingers as set forth in claim 2 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Specification

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The specification is objected to under 37 CFR 1.71 because it is not clear to one 3. ordinary skill in the art how the end cutting edges of the two axially cutting knives are directed toward one another. The specification does not at all discloses how the self centering pharmaceutical pill functions and cut different pill sizes. The specification fails to teach how the components of the self centering pharmaceutical pill are related to one another or how these components function individually or with other components. The specification fails to disclose what encompasses an indexing wheel, torsion fingers, vibration pads and etc. The specification also fails to teach what make the pill cutting device "a self centering pharmaceutical pill cutting g device." It is not clear how the indexing wheel is adjustable. It is not clear how the torsion fingers center keep the pill at center before cutting. It is not clear what is the function of the left and right torsion fingers and how these fingers work. The specification fails to teach how the torsion fingers spring back and what the torsion fingers need to spring back. The specification fails to teach how the indexing wheel holds the pill down. The specification fails to teach how the indexing wheel accommodate multiple pill sizes without change of wheel itself. The structure of the indexing wheel is not disclosed. The specification fails to teach how the indexing wheel can be configured in different shaped pills. The specification also fails to teach how the solenoid activates the blade up and down and how the pills ranging up to 0.187 inch thickness and 0.500 inch diameter can be cut by the pill cutting device. The specification also fails to teach how the vibration pads work and what is the purpose of having vibration pads within the indexing wheel.

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4. The specification is objected to because lack proper content and arrangement, which makes the understanding of the invention difficult.

It is noted the content of the specification is defective and it is not complete. For example, "Brief Description of the Several Views of the Drawing(s)" and "Detailed Description of the Invention" are totally missing from the specification.

Therefore, the invention in general and in particular the critical components of the invention have not been adequately and accurately explained in the specification. The lack of explanation of the invention and its components in the specification renders the proper understanding of the invention and makes the examination of this invention very difficult.

The specification should includes the specific content below:

Content of Specification

- (a) <u>Title of the Invention</u>: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) <u>Cross-References to Related Applications</u>: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement Regarding Federally Sponsored Research and Development</u>: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, <u>Reference to a "Microfiche Appendix</u>": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

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- (e) <u>Background of the Invention</u>: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) <u>Field of the Invention</u>: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37

 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) <u>Brief Description of the Several Views of the Drawing(s)</u>: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) <u>Claim or Claims</u>: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the

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claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) <u>Sequence Listing</u>, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.
- 5. It is noted that the layout of the specification is not in accordance with guidelines of the preferred specification of a utility patent.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFÉRENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

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- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

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- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (i) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

6. Claim 4 is objected to because of the following informalities: in claim 4, "holds pillsdown" should be --holds said pill down-- and "pills ranging up to .187 in thickness and .500 diameter" should be --pills ranging up to 0.187 inch thickness and 0.500 inch diameter--. See claim 4, line 2 and claim 7, lines 2 and 3.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 1-8, the disclosure fails to teach what are the components of the self centering pharmaceutical pill cutting device or how the self centering pharmaceutical pill functions. The specification fails to teach how the components of the self centering

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pharmaceutical pill are related to one another or function individually or with other components. The disclosure fails to disclose what encompasses an indexing wheel, torsion fingers, vibration pads and etc. Regarding claim 1, the specification also fails to teach what make the pill cutting device "a self centering pharmaceutical pill cutting g device." It is not clear how the indexing wheel is adjustable. It is not clear how the torsion fingers center keep the pill at center before cutting. Regarding claim 2, it is not clear what is the function of the left and right torsion fingers and how these fingers work. Regarding claim 3, it is not clear how the torsion fingers spring back and what the torsion fingers need to spring back. Regarding claim 4, it is not clear how the indexing wheel holds the pill down. Regarding claim 5, it is not clear how the indexing wheel accommodate multiple pill sizes without change of wheel itself. The structure of the indexing wheel is not disclosed. Regarding claim 6, it is not clear how the indexing wheel can be configured in different shaped pills. Regarding claim 7, the disclosure fails to teach how the solenoid activates the blade up and down and how the pills ranging up to 0.187 inch thickness and 0.500 inch diameter can be cut by the pill cutting device. Regarding claim 8, it is not clear how the vibration pads work and what is the purpose of having vibration pads within the indexing wheel.

- 9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 10. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding Claim 1, "an adjustable indexing wheel and torsion fingers centering before cutting" is confusing. It is not clear whether the pill or

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torsion fingers are being centered before cutting. Regarding claim 3, "wherein the torsion fingers spring back and allow the ½ inch pill to pass through and exit" is incomplete and it is not what the claims include or exclude or what is being claimed. Regarding claim 7, "the solenoid" lack antecedent basis. Regarding claim 8, "the vibration pads" lacks antecedent basis.

Comment

11. It is noted that claims 1-8 have not been rejected over prior art. However, in view of the issues under 35 US.C. 112, first and second paragraphs, objection to the specification under 37 CFR 1.71, and the objections to the drawings, the allowability of the subjected mater cannot be determined at this time.

Based on disclosure and the prior art, we are not able to determine what would be allowable over the prior art of the record.

12. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yuyama et al. (6,050,064), Atthur et al. (6,244,146), Eric (2003/0084574), Buckley et al. (2002/0179666), Brock (3,877,625), Hipp et al. (4,822,235), Deckert (4,199,863), Hase (6,571,999), and Sharpe teach tablet cutters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ghassem Alie whose telephone number is (571) 272-4501. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Shoap can be reached on (571) 272-4514. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, SEE http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (too-free).

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December 30, 2004

Alian N. Shoap Supervisory Patent Examiner Group 3700 Page 11